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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN R. BAILEY, CHRISTOPHER T. BOYLE,
DENES MARTON, and CHRISTOPHER E. BANAS

Appeal 2011-010516
Application 09/783,633
Technology Center 3700

Before DEMETRA J. MILLS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims drawn to a system comprising an in vivo sensor device and a detection mechanism. The Examiner has rejected the claims as anticipated and obvious over prior art. We have jurisdiction under 35 U.S.C. § 134. We affirm-in-part.

STATEMENT OF THE CASE

The claims are directed to an in vivo sensor device having structural elements composed of different materials, where the materials are characterized by different transition temperatures and transition coefficients. According to the Specification, the device can be implanted into the body and used to monitor a physiological condition or state. Spec. 1: 3-10. The structural members can be fabricated of materials which change shape in response to changes in *in vivo* temperatures, where the changes in shape are detected by an imaging technology to determine in vivo thermal conditions. Spec. 18: 12-23.

Claims 68, 69, 71-78, and 80-85 are pending. Answer 3. The claims stand rejected by the Examiner as follows:

1. Claims 68, 69, and 71-76 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious in view of Freitag[1] (Answer 4);

2. Claims 68, 69, and 71-76 under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious in view of Tu[2] (Answer 5); and

3. Claims 77, 78, and 80-85 under 35 U.S.C. § 103(a) as obvious in view of Orth[3] and Flomenblit[4] (Answer 7).

Claims 68 and 77 are representative and read as follows:

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[1] U.S. Patent No. 5,601,593, issued February 11, 1997.
[2] U.S. Patent No. 6,406,493 B1, issued June 18, 2002.
[3] U.S. Patent No. 5,591,197, issued January 7, 1997.
[4] U.S. Patent No. 5,562,641, issued October 8, 1996.

68. A system comprising:

an in vivo sensor device comprising a plurality of structural elements defining the in-vivo sensor device, the plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, wherein the second transition temperature and the second transition coefficient allows for a change in the geometry or conformation of the second region in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; and a detection mechanism configured to detect the change in the geometry or conformation of the in vivo sensor device, and wherein the second material comprises at least one of a shape memory material and a superelastic material.

77. A system comprising:

an in vivo sensor device comprising a plurality of structural elements defining the in-vivo sensor device, the plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, the second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature; and a

detection mechanism configured to detect the second position of the in vivo sensor device, wherein the second material comprises at least one of a shape memory material and a superelastic material.

CLAIM INTERPRETATION

Claim 68 recites:

> . . . an in vivo sensor device comprising a plurality of structural elements defining the in-vivo sensor device, the plurality of structural elements including a first region being composed of a first material, . . . , the plurality of structural elements including a second region being composed of a second material . . .

Appellant contends that *each* structural element is required by the claim to have a first and second region comprised of first and second materials, respectively. The Examiner challenges this interpretation, finding that the claim is reasonably interpreted to include a first region comprised of structural elements composed of wholly one material and a second region comprised of structural elements composed of wholly a second different material.

To resolve this dispute, we first turn to the language of the claim. The device of claim 68 is recited to have a "plurality of structural elements." The plurality of structural elements is "including a first region" and "including a second region." The plain language of the claim reads on two embodiments:

1) a device with two regions, where a first region has structural elements of one material, and a second region has structural elements of a different material; and

2) a device with structural elements, where each structural element has two regions, one region of one material and a second region of a different material;

This construction is reasonable because the claim recites that the "plurality" is "including" a first and second region which could be met by having individual elements in the plurality having first and second regions, or by having two regions in the plurality, where one region has structural elements of one material and the other region has structural elements of a second material.

The Specification is consistent with this claim construction. For example, Page 17, lines 5-8, reads:

> Where each of the plurality of cantilever members 22 are fabricated of a shape memory material, either individual cantilever members 22 or groups of cantilever members 22 within a single sensor 20 may be fabricated to have different martensite transition temperatures.

Thus, the Specification refers to individual or groups of members being fabricated of different materials.

Appellant contends this interpretation is improper, but does not adequately support their interpretation. For example, Appellant states:

> While Claim 68 includes "a plurality of structural elements", the plurality merely means that there are more than one structural element. Still, <u>each</u> structural element must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material, the second material having a second transition temperature" higher than the first transition temperature.

App. Br. 8. However, claim 68 does not recite that "each structural element" must have a first and second region. Rather, it only requires that plurality have two regions.

1. ANTICIPATION BY FREITAG

Claim 68

Claim 68 is drawn to a system comprising: 1) an in vivo sensor device and 2) a detection mechanism.

The in vivo sensor is recited to comprise a plurality of structural elements including a first region being composed of a first material and a second region composed of a second material. The materials are recited to have different transition temperatures and transition coefficients. The device changes in geometry and conformation as a result of having different transition temperatures and coefficients.

The detection mechanism is recited to be "configured to detect the change in the geometry or conformation of the in vivo sensor device."

The Rejection

The Examiner found that Freitag describes a stent made of struts, which one region of struts has one transition temperature and transition coefficient and a second region of struts has a different transition temperature and transition coefficient. Answer 4. The Examiner found that Freitag's stent acted as a temperature sensor since its struts changed position depending upon the body temperature. *Id.* at 5. As for the detection mechanism, the Examiner found the Freitag disclosed that positioning the

stent with an endoscope which would serve to detect a change in geometry or conformation of the stent. *Id.*

Discussion

In vivo sensor

Appellant contends that the claims require "each structural element must include 'a first region being composed of a first material having a first transition temperature' and 'a second region being composed of a second material, the second material having a second transition temperature' higher than the first transition temperature." App. Br. 8. Appellant contends that Freitag does not describe each structural element as having first and second regions, nor changes in the geometry on the structural element itself, rather than on separate or different structural elements. *Id.*

As discussed above, Appellant's construction of claim 1 is not the broadest reasonable interpretation of the claim as it would be understood by one of ordinary skill in the art in the light of the Specification. The claim is properly construed to cover devices having two regions, where each region has structural elements entirely made of one material or another. Appellant did not dispute that Freitag described regions of struts that meet this limitation. Consequently, we conclude that the Examiner provide sufficient evidence that Freitag describes the claimed in vivo sensor with a plurality of regions as claimed.

Appellant also contends that Freitag does not disclose or enable an "in vivo sensor" as required by claim 68.

> The Applicant described the invention as suitable for monitoring clinically significant physiological events. P. 4, lines 22-23. Indeed, the creation of the sensor is explicitly stated to be for sensing specific physiological conditions. P. 5,

> lines 10-14. Critical to this point is that the sensor is for monitoring *in vivo* conditions; any change in the geometry or conformation of the sensor is a result of changes in conditions of the human subject, not a result of foreign means.

App. Br. 12.

This argument is not persuasive. The claims do not expressly require that *in vivo* sensor to be adapted for sensing physiological conditions. Appellant has not directed us to any language in the claim that would necessitate such an interpretation. Moreover, even were this the case, Freitag describes its device as being composed of materials having a transition temperature of 35°C which expand when heated to body temperature (col. 2, ll. 61-66; col. 3, ll. 34-39; col. 4, ll. 20-22), and thus sense physiological conditions.

Detection mechanism

Appellant also contends that Freitag does not describe a detection mechanism as recited in claim 1. Appellant construes "detection mechanism" to mean an ex vivo mechanism that occurs outside the body. App. Br. 9. Appellant's construction is based on disclosure in the Specification of detection mechanisms which are ex vivo. *Id.* Appellant argues that endoscope relied upon by the Examiner is an in vivo device, not an ex vivo device, and therefore does not meet the claim limitation. App. Br. 9-10.

A patent applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. *In re Paulson*, 30

F.3d 1475, 1480 (Fed. Cir. 1994). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Appellant did not establish that "detection mechanism" is assigned a special meaning in the Specification. The Specification refers to using "*ex vivo* . . . non-invasive detection methodologies." Spec. 7: 11-16; see also, Spec. 14: 29 to 15: 2. However, the Specification does not specifically define "detection mechanism" to be limited to these ex vivo mechanisms, even if such mechanisms are preferred. "[W]hile it is true that claims are to be interpreted *in light of* the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Sjolund v. Musland*, 847 F.2d 1573, 1581 (Fed. Cir. 1988). "[L]imitations are not to be read into the claims from the specification." *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). *See also Enzo Biochem, Inc. v. Applera Corp.,* 599 F.3d 1325, 1342 (Fed. Cir. 2010) ("'it is improper to read limitations from a preferred embodiment described in the specification – even if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.'"). In this case, because Appellant has not established that detection mechanism is defined to mean *ex vivo* mechanism, we decline to import limitations from the Specification into the claims.

"[D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored,

and clarification imposed . . . An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in that way can uncertainties of claim construction be removed, as much as possible, during the administrative process." *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989). As the claim does not expressly recite that the detection means is ex vivo, we decline to construe it so narrowly.

Summary

Because the Examiner established by a preponderance of the evidence that Freitag describes all the limitations of the system of claim 68, and Appellant did not provide adequate rebuttal arguments or evidence, we affirm the rejection of claim 68, and dependent claims 69 and 71-76 which were not argued separately. 37 C.F.R. § 41.37(c)(1)(vii).

2. ANTICIPATION BY TU

Claim 68, 69, and 71-76 stand rejected over Tu. As we have affirmed the rejection of these claims over Freitag, it is unnecessary for us to reach the merits of this rejection. We dismiss it as moot.

3. OBVIOUSNESS IN VIEW OF ORTH & FLOMENBIT

Independent claim 77 has the same requirement of claim 66 with a plurality of structural elements with first and second regions. The claim further recites:

> the second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the first position is coplanar with the

> surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature.

The Examiner found that this limitation met by Orth.

> Orth disclose a piece wise stent with different regions 11, 12, and 20. Regions 11 and 12 expand from a first to a second diameter and region 20 projects radially outward in the form of barbs to engage tissue. Although the two may occur simultaneously as applicant has noted, they also may occur separately at different times (col.9, lines 6-13). The different regions have different independent functions and are actuated separately at different times. Orth discloses actuating the barbs 20 first, instead of second as claimed however.

Answer 14-15.

In other words, the claim requires a second position to project out from the device when the device is in its second expanded diameter ("diametric") state. The Examiner finds the second position is the region 22 containing barb 20 shown in Figure 6A of Orth. Orth teaches that the region 20 containing barb 22 is projected out first, followed by expansion of the stent into a second diametric state. Orth, col. 9, lines 6-13. The Examiner contends this order can be reversed. The Examiner did not provide adequate evidence to support this position.

Figures 6 and 6A of Orth are reproduced below:

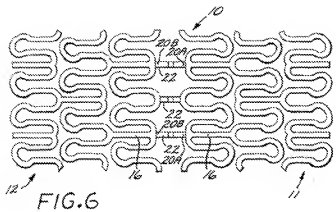

FIG.6

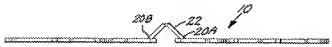

FIG.6A

Figures 6 and 6A depict Orth's stent with sections 10 and 11. Orth teaches that the projecting barb 22 is formed (Fig. 6A) when first stent section 11 and second stent section 12 are forced closer together, thereby causing notched connecting members 20 to deform outwardly and form the projecting barb 22. Orth, col. 9, lines 6-10. According to Orth, "[t]hereafter, the stent can be expanded so that it expands from a first, low profile diameter to a second larger diameter to contact the vessel wall." Orth, Col. 9, lines 10-12. Only after the projecting barb 22 has been formed by the first stent section 11 and the second stent section 12 forcing together, does Orth disclose that the stent is expanded to a second larger diameter (the "second diametric state"). The formation of the projecting barb 22 therefore is not described as forming in the second diametric state as required by the claim. The Examiner did not explain how the stent could be expanded first, without first forcing the stent sections 11 and 12 together. Accordingly, we

are compelled to reverse the rejection of claim 77, and claims 78 and 80-85 which depend on it.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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